2002
UNUSUAL EVENT SUMMARY REPORT

MAY 7, 2003

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The "Health Data Reporting Act of 2002" requires the Department of Health to provide an aggregate report summarizing the type and number of unusual events and other specific events reported by facilities to the Board for Licensing Health Care Facilities. The law also directs the Department to work with representatives of facilities and other interested parties to develop recommendations to improve the collection and assimilation of specific aggregate health care trends over time and to identify system-wide problems for broader quality improvements. These recommendations are to be issued by July 1, 2003.

The General Assembly's intent in passing this legislation was to ensure the delivery of the best medical care for the citizens of Tennessee by minimizing the frequency and severity of unexpected events and improving the delivery of health care services through the collection of meaningful health care data.

Tennessee is one of twenty states that mandates reporting of medical errors or unusual events. Although Tennessee facilities have been required to report for several years, no mechanisms existed to collect, track, or trend the information in order to provide feedback to the facilities. Because no data or feedback was disseminated, limited quality improvements have been identified in this area. At the direction of the Health Commissioner, the Bureau of Health Licensure and Regulation began a process to establish, develop, and implement better systems to simplify reporting and provide a mechanism that would allow feedback to the facilities and a process for comparison of collected data.

The changes implemented prior to the passage of the Reporting Act of 2002 laid a foundation which aided the Department of Health in implementing the new legislation. The most significant changes which occurred over the past three years include:

- Establishment of a work group composed of representatives from facilities, surveyors, nurses, administrators, and attorneys which met monthly for a two-year period beginning in December 1999. The work group developed a definition for "unusual event" and the inclusion/exclusion list for use by facilities and surveyors.

- Development of a manual tracking system in 2000, which later became an electronic system called UIRS (Unusual Incident Reporting System). This extranet computerized reporting system was made available in 2002 for health care facilities to report unusual events.

- Revised facility rules for reporting unusual events in 2001.

- Establishment of the Tennessee Improving Patient Safety Coalition Group (TIPS) in August 2001

With the issuance of the Institute of Medicine's report, *To Err is Human,* in November 1999, recommendations from private organizations and national accrediting organizations such as The Joint Commission on Accreditation of Healthcare Organizations and the National Quality Forum, national attention became focused on the number and types of medical errors and/or unusual events occurring within health care facilities.

The purpose of this report is to provide a summary of the data reported by facilities during 2002 and recommendations based on this data, including system-wide functionality and quality improvements.

An analysis of the 2002 data reveals significant underreporting, particularly by hospitals and other facility types (except for nursing homes). Nursing homes have a history of over-reporting because of the federal fines associated with failure to report. The development of the inclusion and exclusion list by the task force group led to a reduction of unnecessary reporting of events by nursing homes in 2001 and 2002. Hospital reporting began to increase after May 2002, which may be related to the confidentiality protection and reporting requirements placed in the new law that became effective that same month. This rise in hospital reporting does not mean that the incidence of errors is actually increasing. It is likely due to a better system for reporting and documentation.

The top five reported events in 2002 were: falls with fractures, "other," altercations, physical abuse, and verbal abuse.

During 2002, the Tennessee Improving Patient Safety group recommended the adoption of five best practices (See Appendix IV).

Having a good reporting system can help us begin to identify ways to eliminate errors and further improve delivery of care. Aggregate data analyzed at a state level will help identify trends that can benefit all facilities.

INTRODUCTION

Numerous events have shaped the direction of patient safety/error prevention efforts in Tennessee and the nation. Among them, four stand out as particularly noteworthy:

- 1995-1997: The news media began focusing attention on medical accidents[1] starting with the 1994 chemotherapy overdose of Boston Globe health columnist, Betsy Lehman, at the Dana Farber Cancer Institute in Boston.[2] In 1996, a seven year old Florida boy died from an adrenaline overdose during a tonsillectomy[3] and a man had the wrong leg amputated.[4] The public's awareness and concern about medical errors began to grow.

- 1996: The Institute for Healthcare Improvement Breakthrough Series began the Reducing Adverse Drug Events project using quality improvement techniques to systematically reduce adverse drug events in the hospitals.[5] A successful endeavor, it demonstrated across many organizations that the majority of errors could be reduced or eliminated by addressing "systems" issues, rather than focusing on blame or competence questions.

- 1997: The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) unveiled its Sentinel Event Policy, requiring accredited health care organizations to monitor sentinel events and conduct root cause analysis of the events.[6]

- 1999: Release of the Institute of Medicine's (IOM) landmark report, "To Err is Human: Building a Safer Health System".[7] The IOM alerted the health care industry, the public, and policymakers to the large number of preventable patient injuries and deaths occurring in U.S. hospitals. The report estimated that between 44,000 – 98,000 Americans die each year from medical errors, with about half of the deaths being preventable. The report called for policymakers to take action to reduce medical errors in the United States.[8]

Tennessee first began tracking unusual events in the year 2000. Prior to that, as facilities reported unusual events, they were reviewed, investigated when necessary, then placed in a file. The Department did not tabulate any monthly or annual totals. After the IOM report was released in November 1999, the Department convened a group of concerned individuals to define terms, identify issues, and develop guidelines. This was accomplished after several months of exhaustive meetings. This group laid the groundwork for the

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[1] The Massachusetts Health Policy Forum, *Issue Brief Number 10: Medical Errors and Patient Safety in Massachusetts: What is the Role of the Commonwealth?* (Boston, MA: Massachusetts Health Policy Forum, 2000).
[2] "Overdose Still Weigh Heavily at Dana Farber," Boston Globe, December 26, 1995.
[3] "Hospital admits syringe mix-up killed boy", The Palm Beach Post, January 11, 1996.
[4] "Expert: King error a group effort," St. Petersburg Times, September 14, 1995.
[5] Institute for Healthcare Improvement, *Breakthrough Series Guide: Reducing Adverse Drug Events* (Boston, MA: Institute for Healthcare Improvement, 1998).
[6] JCAHO sentinel event policy at www.jcaho.org.
[7] Institute of Medicine, *To Err is Human: Building a Safer System* (Washington, D.C.: National Academy Press, 1999), 180.
[8] National Academy for State Health Policy", Statewide. "Patient Safety Coalitions: A Status Report", May 2002.

realization that the state needed a better system to improve the quality of health care in Tennessee. Tennessee's timeline for improvements to date has been as follows:

December 1999	Task force established to work on the definition of "elopement" which evolved into defining unusual events and drafting interpretive guidelines
April 2001	Grant proposal submitted to Agency for Healthcare Research and Quality (AHRQ) for funding (not awarded)
July 2001	Electronic reporting system established
2001	Leapfrog Group established in Chattanooga
August 2001	Tennessee Improving Patient Safety (TIPS) Committee established
December 2001	Revised rules for reporting unusual events
January 2002	All facilities were capable of inputting their events into UIRS (Unusual Incident Reporting System) a new extranet computerized reporting system
March 2002	Enactment of Public Chapter 508, "Health Data Reporting Act of 2002" passed by the General Assembly
March 2002	Tennessee Improving Patient Safety (TIPS) adopted five "Best Practices" – Seven Components of Abuse Prevention – Wrong Site Surgery – Medication Errors (10 confusing abbreviations to avoid) – Medication Errors (15 ways to lower your dose of medication errors) – Effective and Underused Safety Practices
April 2002	The Health Department began a massive statewide educational campaign for facilities. Educational topics included review of 'Health Data Reporting Act of 2002,' the Department's and facilities' responsibilities as outlined in law, use and availability of "Interpretive Guidelines for Reporting Unusual Events," and electronic reporting. Education was primarily organized through provider associations including the Tennessee Hospital Association, Tennessee Health Care Association, Tennessee Association for Home Care, Tennessee Association of Homes and Services for the Aged, and several large corporate provider training sessions. The Department conducted a total of 18 statewide training programs, constituting 55 hours of actual training to providers. Training continues on a daily basis through individual discussion with department staff and providers.
August 2002	Revised reporting rules for unusual events to comply with law changes – approved by Board for Licensing Health Care Facilities.

Tennessee's definition of an unusual event as stated in law – "An unexpected occurrence or accident resulting in death, life-threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition. An unusual event also includes an event resulting in the abuse of a patient."

The task force further clarified an unusual event by defining "serious injury" or "life-threatening" for guidance in determining what needs to be reported:

> **"Serious injury" or "life-threatening" requires the patient to undergo significant additional diagnostic or treatment measures.**

COMMITTEE ON IMPROVING PATIENT SAFETY (TIPS)

The Tennessee Improving Patient Safety Coalition (TIPS) is a voluntary group of concerned healthcare stakeholders established in August 2001. The broad-based coalition is represented by more than thirty (30) different health care providers, professionals, industry associations, consumers, regulatory and accrediting organizations and purchasers committed to improving patient safety in Tennessee. This group was asked to assist the Department with the goal of improving patient safety in health care facilities in Tennessee and reducing costs, both in terms of human suffering and the economic costs associated with medical errors. This group of individuals has the potential to facilitate learning and collaboration, in addition to providing a forum for leaders to share successful patient safety strategies. The coalition promotes open dialogue about patient safety issues and advocates for an improved culture for reporting and accountability.

First year objectives consisted of:

Objective #1: Provide ongoing leadership in health care quality improvement.

Strategies:

- Review current guidelines for reporting requirements and recommend legislative changes to address confidentiality and civil liability.
- Identify methods of disseminating information.
- Evaluate effects of electronic reporting system.
- Review and support best practice guidelines recommended.
- Identify ways to disseminate information.

Objective #2: Collaborate and coordinate patient safety efforts within the state, with other state agencies, and with other states.

Strategies:

- Determine what each partner can offer the committee.
- Develop a statewide community education initiative on error prevention, error reporting, analysis of data and implementation of patient safety measures. Explore patient partnering.
- Review all avenues for research in health care error prevention at all patient points of care.
- Plan and conduct a summit addressing patient safety and health care error reduction and provide direction for the future.
- Review and provide input on the quarterly progress reports on patient safety improvements.
- Professional reporting.

Objective #3: Develop and review any possible best methods for data analysis and reporting.

Strategies:

- Identify selling points to develop trust in state government.
- Develop a patient safety quality public report (not a score card, aggregate data only). Focus on patient safety improvements.
- Establish a method to communicate best practices periodically to advance loss prevention activities and improve patient care. Collaborate with JCAHO (share de-identified data).

Objective #4: Identify materials on preventing health care errors, patient safety and quality improvements that state regulatory bodies, purchasers, professional associations and societies, health plans, and licensed health care facilities can disseminate, reprint or adopt.

Strategies:

- Determine the type and most effective way to present information on patient safety, health care errors.
- Develop a model patient safety education and training program.
- Encourage medical schools, nursing schools, teaching hospitals to incorporate patient safety training program into their curriculum.

See Appendix VIII - Membership List

FEDERAL/NATIONAL INITIATIVES TO PROMOTE PATIENT SAFETY

There are five major federal reports dealing with patient safety issues to date and many organizations, federal agencies or task forces that were formed to focus on patient safety issues. The following information was taken from a study conducted on patient safety in Maryland.

Reports to date in chronological order:

To Err is Human: Building a Safer Health System. The Institute of Medicine outlined a four-tiered approach to prevent medical mistakes and improve patient safety.[9] The four recommendations are: (1) Establish a national focus to enhance knowledge about patient safety; (2) Identify and learn from errors via a mandatory reporting system and encouragement of voluntary systems; (3) Raise standards and expectations through oversight organizations; and (4) Create safety systems. The report concluded that health care is a decade or more behind other high-risk industries in ensuring basic safety.

Adverse Drug Events. The Government Accounting Office (GAO) responded to a request by Congress regarding medication-related errors. They reported that medication errors are one of the most common types of errors that account for additional health care costs and disabilities. Drug complications account for 19% of adverse medical events. The report cautions, "The magnitude of health risk [from adverse drug events] is uncertain because of limited incidence data."[10]

Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and their Impact. The Quality Interagency Coordination Task Force (QuIC) was charged by President Clinton to respond to the IOM recommendations. The purpose of establishing the QuIC was to coordinate certain federal agencies with an interest in quality health care to explore federal actions to address patient safety. In this report, QuIC responds to each IOM recommendation by outlining federal actions to achieve the goals set forth in IOM report. In addition, the task force proposed additional federal initiatives to improve patient safety which are not adequately addressed by the IOM, including: building public awareness; building purchasers' awareness; working with providers to improve patient safety; using decision-support systems and information technologies and using standardized procedures; checklists; and the results of human factors research.

Crossing the Quality Chasm: A New Health System for the 21st Century.[11] This is another IOM report as a follow-up to the previous publication, *To Err is Human*. This book is a further call to action to improve the health care delivery system as a whole, in all of its quality dimensions.

Making Health Care Safer: A Critical Analysis of Patient Safety Practices. The Agency for Healthcare Research and Quality (AHRQ) published this report in July 2001 in collaboration with the University of California San Francisco/Standford University. The publication includes 79 specific practices that contribute to safer patient care and validates

[9] Ibid.
[10] United States General Accounting Office. Adverse Drug Events: The Magnitude of Health Risk is Uncertain Because of Limited Incidence Data. January 2000.
[11] Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. National Academy Press. 2001.

each one according to current research. Out of 79 practices, 11 practices with the strongest evidence were rated as the most significant in terms of the strength of the evidence. These 11 practices were adopted by TIPS and communicated to all facility types.

Federal/National Organizations Formed:

Advisory Commission on Consumer Protection and Quality in the Health Care Industry

During the Clinton administration, the Advisory Commission on Consumer Protection and Quality in the Health Care Industry was created, "to advise [former-President Clinton] on changes occurring in the health care system at that time and to recommend such measures as may be necessary to promote and assure health care quality value and protect consumers and workers in the health care system."[12] The Commission was comprised of 32 members selected from the private sector. In its very broad summary of recommendations, the Commission set forth several objectives that were aimed at the quality of health care in general. These recommendations addressed providing strong leadership, advancing quality measurement and reporting, creating public-private partnerships, encouraging action by group purchasers, strengthening the hand of consumers, focusing on vulnerable populations, promoting accountability, reducing errors and increasing safety in health care, fostering evidence-based practice and innovation, adapting organizations to change, engaging the health care workforce, and investing in information systems. The Commission also examined evidence of problems in the delivery of quality health care. The areas that were described as examples of gaps in quality were as follows: errors that could be avoided; under-utilization of services; over-utilization of services; and variation in services from one region of the United States to another.

The Institute of Medicine

The Institute of Medicine (IOM) initiated the Quality of Health Care in America project. The initial IOM report, *To Err is Human* (1999), focused on patient safety and offered broad recommendations that the IOM Quality of Health Care in America Committee (formed in June 1998) felt would greatly impact the quality of health care. Additional reports were anticipated regarding other quality-related issues.

Quality Interagency Coordination Taskforce

Doing What Counts for Patient Safety was published by QuIC and it is a formal "road map" for action. Published very shortly after the IOM report, it lays out an agenda of actions and inventories already-existing federal activities for carrying out the IOM recommendations. It directs certain organizations such as the NQF, FDA and the AHRQ to perform activities and report back to the committee on their findings. In instances where QuIC felt there were gaps, they made additional recommendations and offered financial and conceptual solutions. QuIC's report puts the IOM's overarching goals into tangible federal actions. The federal agencies that were involved in this project were: the Department of Commerce, the Department of Defense, the Department of Health and Human Services, the Department of Labor, the Department of Veterans Affairs, the Federal Bureau of Prisons, the Federal Trade Commission, the National Highway Transportation

[12] President's Advisory Commission. Consumer Protection and Quality in the Health Care Industry. June 1998

and Safety Administration, the Office of Personnel Management, the Office of Management and Budget and the United States Coast Guard.

National Quality Forum (NQF)

The NQF is a private, non-profit organization, created to develop and implement a national strategy for quality measurement and reporting in health care. Established as a public-private partnership and incorporated in May of 1999, the NQF has broad participation from all parts of the health care sector, including national, state, regional and local groups representing consumers; public and private purchasers; health care professionals; providers and plans; accrediting bodies; supporting industries; and health care research and improvement organizations.

NQF's ***Serious Reportable Events in Patient Safety*** attempts to establish agreement on a set of serious, preventable adverse events, which might form the basis for a national, state-based event reporting system and could lead to substantial improvements in the quality of patient care. QuIC charged the NQF with this task. Twenty-seven events have been identified by NQF and are currently under review. (See Appendix X).

General Accounting Office

The General Accounting Office (GAO) prepared a report on adverse drug events at the request of Congress. The report describes the different types and causes of adverse drug events (ADEs), the overall incidence and cost of ADEs, and the measures that have been proposed to reduce their number and severity.

The GAO concludes by outlining some of the current and proposed main categories of approaches to reduce medication errors. The major categories of change include: (1) changes in dispensing; (2) changes in packaging and physical characteristics; (3) change in sensitivity to ADEs, through education, communication, etc.; and (4) change in culture.

The Joint Commission on the Accreditation of Health Care Organizations (JCAHO)[13]

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is the nation's oldest and largest accrediting body for health care organizations. They accredit over 19,000 organizations that provide a wide range of services. The process by which hospitals and other health care facilities undergo accreditation by JCAHO involves announced triennial on-site surveys performed by surveyors who are qualified to evaluate an organization's compliance based on applicable standards that have been developed in consultation with health care experts.

The Joint Commission's Board of Commissioners approved for implementation January 1, 2003 a set of six national patient safety goals representing 11 recommendations to improve the safety of patient care in health care organizations. See Appendix - XI

The Veterans Health Administration, Department of Veterans Affairs (VA)

The Veterans Health Administration (VHA) is broadly acknowledged as a model for those health systems that want to improve patient safety. The $20 billion VHA is the

[13] Joint Commission on Accreditation of Healthcare Organizations. http://www.jcaho.org.

nation's largest integrated hospital and health care system. It includes 173 medical centers, approximately 800 outpatient clinics, 134 nursing homes, 206 counseling centers, and assorted other programs.[14] The VA employs 200,000 people, and more than three million veterans a year seek medical services at VA hospitals. After a series of fatal medical errors at VA hospitals, a series of GAO reports led to Congressional hearings that propelled the VA to action. The VA's efforts to uncover mistakes were aided by health care providers' immunity from legal liability. This protection has made it noticeably easier for the VA to encourage error reporting.

In May 2000, a VA Patient Safety Reporting System was modeled after the aviation industry's reporting system. The voluntary, confidential reporting system is designed to encourage health care providers within the VA health care system to report adverse events and near misses. The reporting system is a three-year project costing $8.2 million.

Other patient safety initiatives include the use of root-cause analysis for reportable events, computerized medical records, and provider continuing education requirements in patient safety.

The Department of Health and Human Services (HHS)

The Agency for Healthcare Research and Quality

The Agency for Health Care Research and Quality (AHRQ) published ***Making Health Care Safer: A Critical Analysis of Patient Safety Practices***[15] following the 1999 release of the Institute of Medicine's report. AHRQ commissioned the University of California at San Francisco (UCSF) and Stanford University's Evidence-Based Practice Center (EPC) to review the scientific literature about safety improvement. The charge to the EPC was three-fold; (1) review the existing evidence on practices relevant to improving patient safety; (2) present those findings to the Safe Practices Committee of the Quality Forum (NQF); and (3) grade the practices on the strength of the evidence and the need for further research. Of the 79 patient safety practices reviewed in detail, 11 were most highly rated on the strength of the evidence.

AHRQ recently awarded $50 million in research grants on patient safety and medical error reduction. The projects were awarded to states with existing medical error reporting systems, universities, and health care entities across the country. Also, the HHS Patient Safety Task Force was created in April 2001 to coordinate existing data collection activities of AHRQ, CDC, FDA, and the Centers for Medicare and Medicaid Services (CMS). One goal of the task force is to coordinate reporting systems, such as the CDC's National Nosocomial Infections Surveillance (NNIS) system and FDA's reports on adverse events. AHRQ will also promote evidence-based systems for reducing errors.[16]

The Centers for Disease Control and Prevention

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[14] The Veterans Health Administration. http://www.va.gov/About_VA/Orgs/VHA/index.htm.

[15] KG Shojania, BW Duncan, KM McDonald, et al., eds. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment No. 43 (Prepared by the University of California at San Francisco-Stanford Evidence-based Practice Center under Contract No 290-97-0013), AHRQ Publication No. 01-E058, Rockville, MD: Agency for Healthcare Research and Quality. July 2001.

[16] United States Department of Health and Human Services, Agency for Healthcare Research and Quality. *Patient Safety Task Force Fact Sheet.* http://www.ahrq.gov/qual/taskforce/psfactst.htm.

The Centers for Disease Control and Prevention (CDC) has a system for reporting nosocomial infections, or hospital-acquired infections. The National Nosocomial Infections Surveillance (NNIS) is a voluntary, hospital-based reporting system established to monitor hospital-acquired infections and to guide the prevention efforts of infection control practitioners. NNIS began in 1970 with 62 participating hospitals in 31 states. By 1999, 285 hospitals in 42 states participated in NNIS. All NNIS hospitals have 100 or more beds and tend to be larger than other U.S. hospitals. Infection control practitioners receive 28 hours of training at CDC and are invited to attend a biennial conference. Infection control practictioners are periodically surveyed to determine their number and spectrum of activities. The CDC recommends that hospitals should have at least one full-time infection control practitioner for every 250 occupied hospital beds.[17] The CDC in conjunction with the FDA manages the vaccine adverse event reporting system (VAERS).

The United States Food and Drug Administration

The Food and Drug Administration (FDA) forms a vital part of the network currently in place for the reporting of adverse medical events. The agency closely monitors marketed human medical products for unexpected events as a part of its postmarketing surveillance. This surveillance is conducted soon after medical products receive FDA approval for distribution.

The FDA hosts several reporting systems including, MedWatch, Adverse Event Reporting System (AERS), the Drug Quality Reporting System, and the Center for Biologics Evaluation and Research (CBER). The CBER maintains an error and accident reporting system, the Vaccine Adverse Event Reporting System (VAERS), the Manufacturer and User Device Experience (MAUDE) Database and a reporting system for blood and blood components.

Congressional Action

Several bills have been introduced over the past three to four years in both the U.S. Senate and the House of Representatives related to patient safety. The 106th Congress was responsible for approximately six bills having to do with patient safety issues. The 107th Congress has introduced nine bills to date. The subjects include, but are not limited to, the description and requirements of various reporting systems, the establishment of a patient safety center within AHRQ, informatics grant programs to hospitals and skilled nursing facilities, the public disclosure of clinican staffing and performance or outcomes data, the provision of programs to improve nurse retention, and provisions to limit the number of mandatory overtime hours a nurse may be required to work.

Private Initiatives

The Leapfrog Group

The Leapfrog Group is a consortium of approximately 80 Fortune 500 companies and other large private and public health care purchasers. In November 2000, the Leapfrog Group initiated a national effort to recognize and reward providers for advances in patient

[17] CDC.MMWR. Monitoring Hospital-Acquired Infections to Promote Patient Safety – United States, 1990-1999. March 03, 2000

safety and to educate employees, retirees, and families about the importance of hospitals' efforts in this area. The current focus on improving patient safety is tailored to three areas: computerized physician order entry; evidence-based hospital referral; and intensive care unit physician staffing.

U.S. Pharmacopeia

U.S. Pharmacopeia is a non-profit, volunteer-based, private organization that works closely with health care practitioners and institutions, regulatory agencies, professional organizations and the pharmaceutical industry to provide education about patient safety. U.S. Pharmacopeia's (USP) MedMARX is a national, Internet-based, interactive medication error prevention tool that enables hospitals using MedMARX to anonymously report and track medication errors in a standardized format. Approximately 250 hospitals use this system, including the Department of Veterans Affairs and the Department of Defense. The system allows the participating facilities to not only report medication errors anonymously, but to retrieve data for their own facility and obtain non-identifiable comparative information on other participating hospitals. An e-mail system allows USP to communicate with users and for users to communicate with USP, while still remaining anonymous by the use of a facility identifier. USP can issue alerts to a single user or a group. Another feature of the MedMARX system is that it also provides a template for the Joint Commission's model for conducting a root cause analysis.

Another reporting system, the Medication Errors Reporting (MER) system, is administered by USP. This system was designed for individual practitioners to report medication errors using an internet-based tool.

The National Patient Safety Foundation

The National Patient Safety Foundation (NPSF) was developed by the American Medical Association in response to the patient safety movement. The mission of the group is to improve patient safety though a core body of knowledge and pathways to apply that knowledge; improve the culture of awareness towards patient safety; and educate the public. The NPSF has issued several grants in an attempt to foster research identifying the underlying safety problems and causes of those problems. The NPSF supports that patient safety should focus on the system of preventing medical errors, and not on individual providers. The NPSF has issued two publications assessing patient safety studies that are currently underway or that have been conducted.[18]

[18] "Lessons in Patient Safety" and "Current Research on Patient Safety in the United States". http://www.npsf.org.

ELECTRONIC REPORTING SYSTEM (UIRS)

The UIRS System was developed 1) to improve the reporting of unusual events so that appropriate and accurate reports are filed, 2) to ensure that follow-up on reports of serious adverse events is more timely, and 3) to return information on improving patient safety to health care providers and State administrators.

The consistency of the data has increased through the use of a standard format and guidelines. The Department is continually addressing the need to improve the reporting, the analysis of the data collected, and the development of best practices.

In order to clarify the Department's interpretation of the term "event of an unusual nature," the Department developed and published a reference manual entitled "Interpretative Guidelines" for use by facility and Department staff. The manual provides guidelines by assigning a unique code for each reportable event. The manual also contains inclusion and exclusion lists for every occurrence code, providing specific examples of reportable and non-reportable events.

There are multiple components to the Unusual Incident Reporting System (UIRS): data entry, notification, review, assignment, scheduling, and reporting. Initially the facility connects to the UIRS website and logs in with a Department issued user name and password specific to each licensed entity. The entire session from the point of entering authentication credentials is encrypted from the facility's computer to the web-server. All data transmitted across this connection is encrypted while in transit.

Once the credentials have been verified, the facility has multiple options. They may review existing reports online for their facility or enter a new report. If they choose to submit a new report, they have an online form that they must complete. Certain fields are mandatory and must be completed. Other fields are standardized and data driven for the purpose of efficiency and consistency. The facility will have the opportunity to review their electronic report before confirming the submission to the Department. Once the report is confirmed and submitted to the State, a transmission number is returned to the facility both on the web-site and through e-mail if the facility had chosen to submit their e-mail with the report. No event specific information other than a date and time stamp with the transmission number verifying the submission is sent to the facility.

Once an event is submitted through UIRS, the appropriate Department personnel receive an alert notifying them that a new submission is ready for review. Department staff will review the submission and either accept or return the report as incomplete. The facility will receive an e-mail alert notifying them of a status change to their report if they included e-mail information with their report. However, the status change is also reflected on the website and it is the facility's responsibility to check the status and assure the completeness of their report prior to the end of the required seven-day reporting period from the date of the event. If the report is returned incomplete to the facility, they then have the opportunity to resubmit the report with changes. The Department's regional office may contact the facility with an explanation of what information is lacking in order to assist with the reporting process.

Once a report is submitted and accepted by the Department, the facility will be responsible for completing additional web forms. If the event is a result of a medication error, then a

medication error supplement is available online to be completed. All accepted reports must have a corrective action plan completed and accepted within 40 days of the event. The corrective action plan form is available on the website for completion. Up to three basal causes can be selected from a pre-defined list. Additional information must be completed in summary form regarding the actual plan of correction and the measures of effectiveness. The corrective action plan goes through the same review and acceptance process with the Department as the initial event report. The only difference is that the corrective action plan may have its submission deferred until the facility has completed all their changes to the form, thereby giving the facility opportunities to review and update the corrective action plan before submission.

The corrective action plan will be reviewed by the Department when submitted. The Department has an opportunity to request changes from the facility before the reporting term is expired. The UIRS site has visual queues for the facility to help them identify the status of the reports they have submitted. Each record is color-coded, has a status description, and presents additional information when hovering over the status codes. Once an event report, medication errors supplement, and corrective action plan are completed and accepted, the report is marked as complete and no further action is required by the facility on that event.

The Department has additional components available for its use in UIRS. The Department has the ability to schedule surveys, assign responsible personnel, change the status of a report and its components, and complete information on the behalf of facilities if they are unable to report electronically. Both the facilities and the Department have reports available to them on the website. The facility reports are specific to their facility or are statewide aggregate reports focusing on their provider type or all provider types together. These reports focus on the types of occurrences reported and the basal causes reported. The Department has the facility reports available to them, as well as management reports related to the completeness of reports in the queue.

The Division of Health Care Facilities compiles a monthly summary report of all unusual events reported. The summary contains the total number of events by category and facility type, and any harm or outcome. The unusual event reports from facilities were sent to regional offices until January 2002, when it was moved to the central office for intake and assignment of a priority code. Some occurrence codes are assigned a priority code electronically and the appropriate regional office is notified immediately by e-mail. Priority 1 and 2 are sent as an alert to supervisors and regional administrators.

The UIRS "website" resides on a web-server and functions as an extranet application statewide for health care facilities to connect to and self-report unusual events. These reports populate a database that generates a log on the State's intranet component of the UIRS website. From here, the staff assigns an investigation priority and tracks the event through resolution.

All patient-level data are protected appropriately to ensure confidentiality with encryption firewalls and password protection. The system ensures that privacy and security requirements of HIPAA (Health Insurance Portability and Accountability Act) are met or exceeded. The following explains how the system security is organized.

Regarding data within the Department, each regional office and the central office are protected on the State of Tennessee Wide Area Network by both firewalls at Egress points

managed by the State of Tennessee and internally on our own homogeneous network. Only those with an appropriate authentication key and encryption client can connect with our network.

As for the web-based extranet application, a user list exists for the facilities so they can authenticate themselves to have access to the web-based form. Users of UIRS only have access to their own information. The authentication process assures that no facility will have the ability to look up another facility's events. In addition, 128-bit secure socket layer technology is utilized on the website to encrypt and protect the data while in transit across the Internet to the facilities web browser. To ensure the integrity and control of the data, no caching is permitted of the website data on an end-user machine using the web-based application.

DATA SUMMARY

The past three years saw an exponential increase in the number of unusual events reported by hospitals, an over fifty percent reduction in reporting by nursing homes and homes for the aged, and a seventy-five percent increase by all other facility types. Much of the change is due to emphasis the Department has placed on the reporting of unusual events, and educational sessions conducted for facilities over the past two years.

For example, the decline in nursing home reporting is due, primarily, to the publication of interpretative guidelines that defined what should be reported. Conversely, reporting by hospitals improved, as training became available through the period.

Table 1.
Number of Unusual Incidents Reported, By Facility Type, 2000-2002, Tennessee

Facility Type	Year		
	2000	2001	2002
All	6,516	4,068	3,839
Hospitals	42	119	616
Nursing Homes	6,099	3,457	2,749
Homes for Aged	141	53	63
Assisted Care Living Facility	127	248	255
Intermediate Care Facility/MR	95	176	115
Other	12	15	41

The impact of training and reporting experience can be seen in the shift in the severity of the incidents reported in 2002 as compared to 2001. While the number of reports declined slightly from 2001 to 2002, the number of "Priority 1-3" incidents grew from 24.5 percent of the total in 2001 to 73.4 percent in 2002.

Table 2.
Percent Distribution of Reported Incidents by Category, 2001 and 2002

	Year	
Category of Event	2001	2002
Total	100.0	100.0
Priority 1	8.6	15.6
Priority 2	6.7	11.9
Priority 3	9.2	45.9
Priority 4	33.6	15.9
Priority 5	41.9	10.8

<u>UIRS Reporting by Licensed Nursing Homes in 2002</u>

This analysis looks at the reporting of 349 licensed nursing homes operating in Tennessee in 2002. At least one unusual incident report was filed by 306 facilities. By number of licensed beds, reporting in 2002 is summarized in Table 3.

Table 3.
Number of Licensed Nursing Homes According to Number of Licensed Beds,
And UIRS Reporting Status, Tennessee, 2002

Bed Size	Number of Facilities	Reporting one or more events	No Events Reported	Percent Reporting
Total	349	306	43	87.8
< 50	50	33	17	66.0
50-99	95	83	12	87.4
100-149	129	118	11	91.5
150-199	56	55	1	98.2
> 200	19	17	2	89.5

As expected, the reporting percentage varied directly with bed size. Given the high occupancy rates experienced by nursing homes, a reportable event is more likely, everything else equal, in a facility with more patients.

Looking at facility location according to grand division, reporting for 2002 is summarized in Table 4.

Table 4.
Number of Nursing Homes According to Grand Division and UIRS Reporting Status,
Tennessee, 2002

		Grand Division		
Status		East	Middle	West
Total	349	126	131	92
Reported at least one event	306	113	115	78
Percent	87.8	89.7	87.8	84.8

Middle and West Tennessee each had one large (200+ beds) non-reporting facility.

<u>UIRS reporting by licensed hospitals in 2002</u>

There were 151 licensed hospitals in Tennessee in 2002. The likelihood of a reportable event occurring in a facility is a function of the size, mission, and the training and diligence of the facility's staff. Only 96 hospitals reported an incident that qualified as a "reportable" event. By general category of service, reporting in 2002 is summarized in Table 5.

Table 5.
Number of Licensed Hospitals According to Number of Licensed Beds,
and UIRS Reporting Status, Tennessee, 2002

Hospital Type	Number of Facilities	Reporting one or more events	No Events Reported	Percent Reporting
Total Licensed	151	96	55	63.6
Short-Term	128	88	40	68.7
Licensed Beds				
< 100	57	31	26	54.4
100-249	44	32	12	72.7

> 250	27	25	2	92.6
Other*	23	8	15	34.8

*Other – Rehabilitation hospitals or specialty (not acute care).

Looking at facility location according to grand division, reporting for 2002 is summarized in Table 6.

Table 6.
Number of Hospitals According to Grand Division and UIRS Reporting Status, Tennessee, 2002

		Grand Division		
Status		East	Middle	West
Total	151	56	53	42
Reported at least one event	96	34	37	25
Percent	63.6	60.1	69.8	59.5

Although Middle Tennessee had the greatest percentage of hospitals reporting, East Tennessee had the greatest number of reported events.

Table 7.
Number of UIRS Reports by Month of Event and Grand Division of Facility, 2002**

	Grand Division			
Month of Event	East	Middle	West	Total
Jan	17	10	1	28
Feb	18	12	2	32
Mar	7	7	5	19
Apr	17	7	7	31
May	30	8	13	51
Jun	29	9	23	61
Jul	28	11	19	58
Aug	20	20	18	58
Sep	19	32	16	67
Oct	23	19	11	53
Nov	28	22	13	63
Dec	28	11	9	48
Total	264	168	137	569

**Events that occurred in 2001 but reported in 2002 are excluded from this table.

Following the start of training in May 2002, the number of reported events for each subsequent month remained greater than those prior to training.

Hospital Underreporting

The failure of over a third of licensed facilities to report a single UIRS event indicates an underreporting problem. However, based on the licensed bed size data above, the proportion of all patients in those non-reporting facilities may be small and the impact on

event reporting, therefore, may be miminal. For example, from January through June 2002, the percent of patients in short-term, non-reporting hospitals was only 9.6 percent of all short-term patients. Conversely, most large acute care facilities are reporting a few, but not all, reportable events.

Estimates vary on the percent of all hospital admissions that experience a reportable event. The Institute of Medicine cites two studies that found 2.9 percent (New York, 1984) and 3.7 percent (Colorado and Utah, 1992) of admissions experience an "injury caused by medical mismanagement."

In Tennessee, during a six-month period in 2002, there were 395,270 inpatient discharges from short-term, acute care hospitals. Using this data, the Department identified 25,690 discharges (6.5% of total), during which patients experienced one or more adverse events during their hospital stay. Each hospital inpatient discharge is reported to the Department and included are codes that can identify up to ten different diagnoses. Using the ICD-9-CM coding structure, certain diagnoses can be flagged as "Potentially Reportable Events."

Theoretically, more than one event could occur during each hospital stay. Each diagnosis field was inspected for a relevant code, and the results were categorized as follows:

Table 8.
Number of Potentially Reportable Events, January-June, 2002,
All Licensed Acute Care Hospitals, Tennessee

	Number of Events		
Category*	Non-Reporters	Reporters	All
Total	2,352	28,460	30,812
Medication events	476	3,588	4,064
Complications peculiar to certain specified procedures.	533	9,650	10,183
Complications affecting specified body systems.	491	5,903	6,394
Other Complications of Procedures	747	8,290	9,037
Complications of Medical Care	52	544	596
Accidental cut, puncture, etc performed during medical care	51	470	521
Foreign object left in during procedure	2	11	13
Failure of sterile precautions during a procedure	0	0	0
Failure in dosage	0	0	0
Mechanical failure of instrument or apparatus during procedure.	0	4	4

*See Appendix for definitions of the categories

For this six-month period of time, 30,812 potentially reportable events were identified. For a twelve-month period, this would equate to as many as 61,624 events that occurred during 2002 as compared to the 616 that were actually reported in the UIRS system. Even if one used a smaller percentage of the estimated number of reportable events identified by the hospital discharge data, it would reflect a gross amount of underreporting.

FUTURE INITIATIVES

As stated earlier, the primary intent of reporting unusual events is to improve the delivery of the best medical care for the citizens of Tennessee by identifying the types of occurrences and by developing a method for reducing the occurrences of medical errors. All facilities are required to submit a plan of correction, a basal cause analysis (root cause), and measures of effectiveness to ensure that the facility has assessed system weaknesses and to verify that corrective actions were taken.

The Department will undertake the following initiatives in order to carry out the intent of the law:

- As stated in this report, there is an underreporting problem by some facility types, which limits data analysis. The Department will continue to provide educational sessions throughout the year and provide reporting analysis regularly to the Board for Licensing Health Care Facilities.

- As identified, completeness of reports and correctly written action plans and measures of effectiveness are essential in providing data that is reliable and usable. The Department, in collaboration with facilities, will develop definitions and detailed examples for basal cause, action plan, and measures of effectiveness.

- The Department will continue to monitor the number of facilities that report electronically and to encourage electronic reporting to support consistent data received.

- The Department will continue to monitor compliance with action plans and measures of effectiveness and sanction those facilities that fail to carry out their stated action plans. This discipline may be in the form of deficiencies or penalties that will be publicly identified.

- The Department will further refine the UIRS system to improve in data storage and collection.

- The TIPS Committee will continue to meet quarterly to assist the Department in identifying “best practices”, and assisting with educational approaches for the communities.

- The Department will continue to work on analysis of data with the Department’s Bureau of Health Informatics.

- The Department, in collaboration with TIPS and facilities, will develop a strategy that addresses unnecessary reporting by facilities.

AREAS OF IMPROVEMENT

1. Completeness of Reporting in UIRS.

   One of the areas of concern during 2002 was the completeness of reports submitted by facilities, and the information entered by survey staff. If data are not reported completely and accurately, it is difficult, if not impossible, to know the statewide frequency of unusual events, occurrences per facility type, categories of causes, or if facilities have developed an appropriate action plan related to the outcomes of the investigation. This impedes the determination of which occurrence codes should have the highest priority for quality improvement efforts, and interferes with efforts to measure improvements that have occurred as a result of information derived from UIRS. In recognizing the inconsistencies in data received, the Department made several upgrades to UIRS, including adding a field to allow providers to submit a corrective action plan electronically. By submitting electronically, the Department has created a listing of standardized causes for events for providers to choose from, if applicable. This addition has already realized some improvements in determining the causes of events occurring in Tennessee facilities and should continue to improve over time.

2. Reporting of Unusual Events

   Facilities, other than nursing homes, have underreported unusual events over the years. Several reasons have been stated for not reporting, such as:

   - Fear of litigation
   - Consumers' inability to understand data
   - Inadequate quality improvement process within the facility – root cause analysis not investigated thoroughly
   - Professional caregivers' fear of punitive actions
   - Lack of support of a quality process

   Several of these reasons have been addressed in the Health Data Reporting Act of 2002, by mandating the confidentiality of the information and requiring aggregate data reporting annually. The underreporting by facility types should improve over the next year.

   The Department recognizes that hospitals underreport by reviewing the ICD-9 codes reported with the hospital discharge data submitted to the state annually. However, due to the timeliness of submitting hospital discharge data, the comparison with UIRS data is hindered in matching this data with the UIRS occurrence codes. In fact, according to the 1999 Tennessee hospital discharge data, there were at least 29,000 preventable adverse events reported and over 2,900 of these adverse events were preventable deaths.

3. Writing an appropriate action plan and identifying measures of effectiveness.

   In reviewing action plans and measures of effectiveness submitted by facilities and those that the surveyor reviewed and accepted, many are not written correctly and do not reflect the problems identified in the analysis. These are so poorly written that the data do not provide a stable, reliable basis for analysis. The way in which this data is collected in the UIRS may add to the confusion and utilization of information.

   Until a comprehensive educational program is conducted both for facilities and state survey staff concerning the writing of action plans and identifying measures of effectiveness, there will be very few improvements made in the quality of reporting or care. There have been many improvements in our process due to the educational training completed during 2002. Because of a persistent lack of understanding and lack of knowledge of the components and development of an appropriate action plan and measures of effectiveness, the Department and facilities will continue to dedicate as much time to this effort as possible.

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